

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE ZOLL MEDICAL CORP. BASE POWERCHARGER 4X4

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November 2000

Approved for public release; distribution unlimited.

20010510 013

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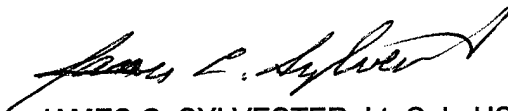
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REPORT DOCUMENTATION PAGE					Form Approved OMB No. 0704-01-0188	
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1. REPORT DATE (DD-MM-YYYY) 30 Nov 2000		2. REPORT TYPE Final			3. DATES COVERED (From - To) Jul 2000-Nov 2000	
4. TITLE AND SUBTITLE TESTING AND EVALUATION OF THE ZOLL MEDICAL CORP. BASE POWERCHARGER 4X4.					5a. CONTRACT NUMBER	
					5b. GRANT NUMBER	
					5c. PROGRAM ELEMENT NUMBER 62202F	
					5d. PROJECT NUMBER 7184	
6. AUTHORS Robert E. Eshelman, TSgt, USAF					5e. TASK NUMBER 56	
					5f. WORK UNIT NUMBER 01	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Air Force Research Laboratory Human Effectiveness Directorate Biodynamics Protection Division 2504 Gillingham Dr. STE 25 Brooks AFB, TX 78235-5104					8. PERFORMING ORGANIZATION REPORT NUMBER AFRL-HE-BR-TR-2001-0072	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)					10. SPONSOR/MONITOR'S ACRONYM(S)	
					11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; distribution unlimited.						
13. SUPPLEMENTARY NOTES						
14. ABSTRACT The ZOLL Base PowerCharger 4x4 is a battery charger and testing system designed for management with PD 4410 battery packs used in ZOLL Medical Corporation M-Series resuscitation devises. The charger provides four battery charging/testing compartments. Up to four battery packs may be charged or tested in any combination at one time. The ZOLL Base PowerCharger 4x4 with Auto Test automatically tests battery capacity with each battery recharge. In addition, it illuminates the Batt. Ready indicator when the battery is fully charged and capable of powering a PD 4410 battery for approximately 2.0 hours in monitor mode. With Auto Test, the full charging cycle is comple in 8 hours or less. The ZOLL Base PowerCharger 4x4 operates using 115 VAC/60 Hz power.						
15. SUBJECT TERMS Aeromedical Battery Charger Defibrillator Aircraft Battery Support System ZOLL Airworthiness Cardiac Monitor						
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT		18. NUMBER OF PAGES	
a. REPORT	b. ABSTRACT	c. THIS PAGE	UL		19a. NAME OF RESPONSIBLE PERSON TSgt Robert E. Eshelman	
unclassified	unclassified	unclassified			19b. TELEPHONE NUMBER (Include area code) (210) 536-2937	

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ACKNOWLEDGMENTS

The author would like to thank those who helped and provided advice during the evaluation of the ZOLL Medical Corp., PowerCharger^{4X4}.

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TESTING AND EVALUATION OF THE ZOLL MEDICAL, CORP. ZOLL BASE POWERCHARGER ^{4x4}

BACKGROUND

ZOLL Medical, Corp., approached Air Force Medical Equipment Development (AFMED) in evaluating and approving ZOLL Medical Corp., Base PowerCharger ^{4x4} with Auto Test and the ZOLL Smart Batteries for use onboard USAF aeromedical evacuation aircraft. Specific components of the PowerCharger ^{4x4} unit that underwent evaluation included ZOLL Medical Corp., PowerCharger ^{4x4} (Model 8050-0002-30 Military ^{4x4} Base PowerCharger), and four PD 4410 rechargeable Smart batteries (model 8004-0103-30). The ZOLL Base PowerCharger ^{4x4} represents the latest commercial off-the-shelf (COTS) technology and is designed to be used with the ZOLL M Series, Cardiac Monitor/Monophasic & Biphasic Defibrillator/Pacer/SpO₂/AED. Throughout this report, the term EUT (equipment under test) refers to the ZOLL Base PowerCharger ^{4x4} and all internal and external components.

DESCRIPTION

(Partially extracted from ZOLL Base PowerCharger ^{4x4} Operator's Manual) (1)

The ZOLL Base PowerCharger ^{4x4} is a battery charger and testing system designed for management of PD 4410 battery packs used in ZOLL Medical Corporation resuscitation devices. The EUT provides four battery charging/testing compartments. Up to four battery packs may be charged or tested in any combination at one time. The ZOLL Base PowerCharger ^{4x4} with Auto Test automatically tests battery capacity with each battery recharge. In addition, the outer case of the PowerCharger ^{4x4} illuminates the **Batt. Ready** indicator when the battery is fully charged and capable of powering a ZOLL M Series MonoPhasic or BiPhasic cardiac monitor for approximately 2.0 hours in monitor mode. Fully charged batteries whose capacity is insufficient to power the devices for this period of time will cause a **Fault** light to illuminate. With AutoTest, the full charging cycle is complete in 8 hours or less.

Operating Controls and Indicators

1. Power

Illuminates when the Base PowerCharger is connected to live AC mains and the unit is ready for charging and/or testing.

2. **Charger On**

Illuminates when a battery is properly installed in the corresponding battery charging/testing compartment and the test/charge cycle is in progress.

Illuminates with the **TESTING** light during AutoTest and recharge of the battery.

There are four **Charger On** indicator lights. Each one corresponds to the battery charging/testing compartment directly adjacent to it.

3. **Batt. Ready**

Illuminates at the end of a test/charge cycle (8 hours or less). Indicates that the battery has been charged to 100% of its present capacity and is ready for use.

Illuminates at the end of a battery test or battery compartment test and remains lit as long as battery remains in compartment. Indicates the battery compartment or battery has passed the capacity test and is operating properly. There are four **Batt. Ready** indicator lights. Each one corresponds to the battery charging/testing compartment directly adjacent to it.

4. **Fault**

Illuminates with the **Testing** light, when battery capacity test fails. Also, illuminates when a battery compartment or any other failure occurs.

There are four **Fault** indicator lights. Each one corresponds to the battery charging/testing compartment directly adjacent to it.

5. **Testing**

Illuminates when either battery capacity test cycle is in progress or battery compartment test is completed.

Illuminates with the **Fault** light to indicate a battery that has failed the capacity test.

There are four **Testing** indicator lights. Each one corresponds to the battery charging/testing compartment directly adjacent to it.

Illuminates with the **Charger On** light during AutoTest and recharge of the battery.

6. **Test button**

Initiates battery test cycle or battery compartment test. The battery capacity test cycle automatically charges, discharges and recharges the battery.

If a battery is installed in the battery compartment and the corresponding **Test** button is pressed, a capacity test is performed. If the battery compartment is empty and the corresponding **Test** button is pressed, a compartment test is performed and an audible tone will sound indicating passed.

There are four **Test** buttons. Each one corresponds to the battery charging/testing compartment directly adjacent to it.

Battery Auto Test Charging

ZOLL PD 4410 Smart batteries may be charged in any of the four battery compartments. Each battery charge compartment operates independently of the others. Four batteries may be charged simultaneously. Installation or removal of adjacent batteries will not affect the ongoing charging of batteries in other compartments. Correct placement of the battery into any compartment will automatically initiate the test and charging cycle.

To turn the Base PowerCharger ^{4x4} on, plug the power cord into live AC mains. All indicator lights will illuminate for approximately 5 seconds and then go off. An audible tone will sound indicating that the unit has passed its self-test, and the **Power** light will remain lit.

Battery Management

The ZOLL PD 4410 Smart Battery Pack is a five-cell assembly of sealed lead-acid batteries specifically designed for use with ZOLL Monitor/Defibrillator devices. Lead acid battery packs require full recharging after use. Continuous short cycle recharging will result in reduced capacity and early battery pack failure.

Battery Life Expectancy

Frequency of use, number of batteries used, and the pattern of discharging and recharging batteries contribute to the loss of battery charge capacity. Because of this, ZOLL recommends that operators replace and discard used batteries on a preventive, scheduled basis. The most effective preventive replacement interval should be based on anticipated use patterns, battery pack testing results and experience with the device in actual operation. ZOLL recommends battery replacement every eighteen months or sooner.

Specifications

The following information defines general specifications of the ZOLL Base PowerCharger ^{4x4}
Size: 13 1/4 in. length x 12 1/8 in. width x 4.1/2 in. high. Weight: 9.19 kgs (20.26 lbs) with four batteries and AC power cord.

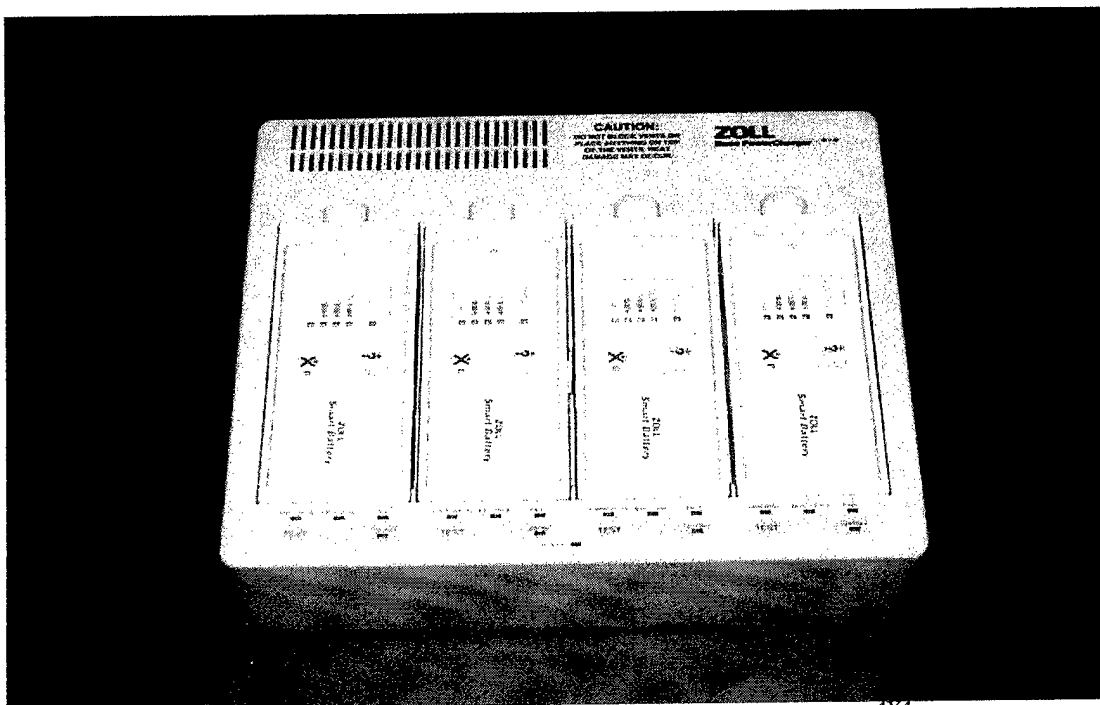


Figure 1. ZOLL Medical Corp., Base PowerCharger 4x4

PROCEDURES

Test methods and performance criteria were derived from manufacturer's literature (1), various military standards (2-4,10), and nationally recognized performance guidelines (5). The Air Force Medical Equipment Development Laboratory Flight Performance Evaluation Procedures Guide and Testing Standards describes additional safety and human interface issues to be considered during equipment testing (6,11). A test setup and performance check were developed specifically for this product to verify proper functioning of the equipment under various testing conditions.

The EUT was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection
2. Vibration
3. Electromagnetic Interference (EMI)
4. Thermal/Humidity Environmental Conditions, encompassing:
 - a. Hot Operation

- b. Cold Operation
 - c. Humidity
 - d. Hot Temperature Storage
 - e. Cold Temperature Storage
5. Hypobaric
- a. Cabin Pressure/Altitude
 - b. Rapid Decompression to Ambient
6. Explosive Atmosphere
7. Airborne Feasibility/Performance

INITIAL INSPECTION AND TEST PREPARATION

The EUT was inspected for quality of workmanship, production techniques, and possible damage incurred during shipment.

The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (7), AFI 41-203, Electrical Shock Hazards (8), and AFI 41-201, Equipment Management in Hospitals (9). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.

The EUT was examined to ensure it met basic requirements for human factor design as outlined in MIL-STD1472 F (4).

A test setup and performance check was developed to evaluate the operation of the EUT in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP & PERFORMANCE CHECK

The EUT was placed on a level surface and connected to 115 VAC/60 Hz outlet. Four PD 4410 Smart batteries were installed into battery compartments making sure the batteries were fully seated. A Battery Auto Test Charging procedure was performed as described in manufacturer's owner's manual. Batteries were then removed and a Battery Compartment Testing procedure was initiated as outlined in manufacturer's operator's manual.

VIBRATION

Vibration testing is critical to determine the resistance of equipment to vibrational stresses expected in its shipment and application environments. Testing was conducted on an Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30, and shaker model R16W. This testing involved a set of operational tests performed along each of the EUT's three axes - X, Y, and Z with the EUT mounted on the vibration table (Fig. 3). It was subjected to vibration curves (figures 6-10) with similar levels and lengths as those derived from MIL-STD 810F, Category 514.4-16 and 514.4-17.

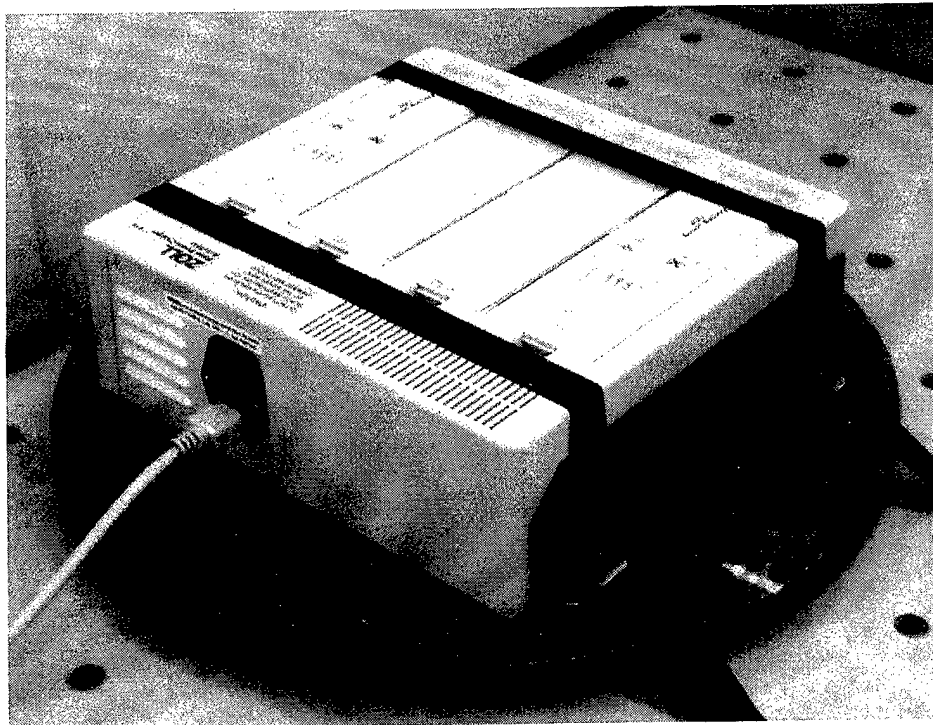


Figure 2. Vibration Table Mounting

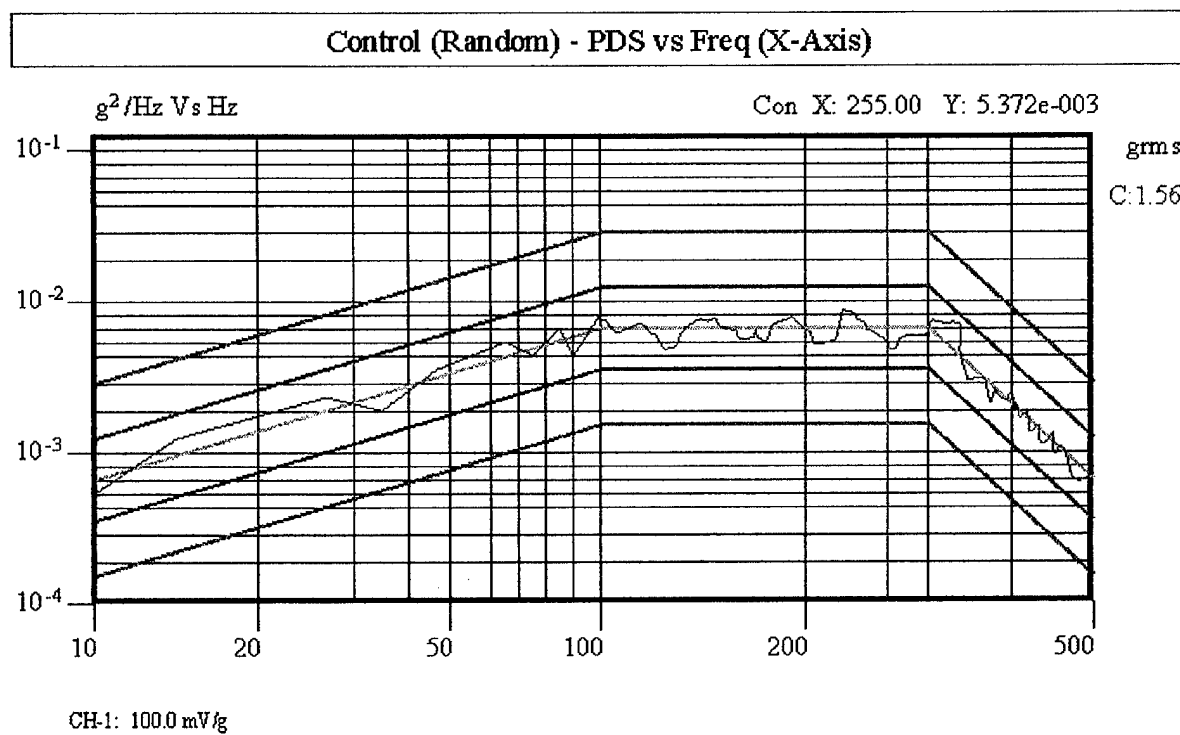
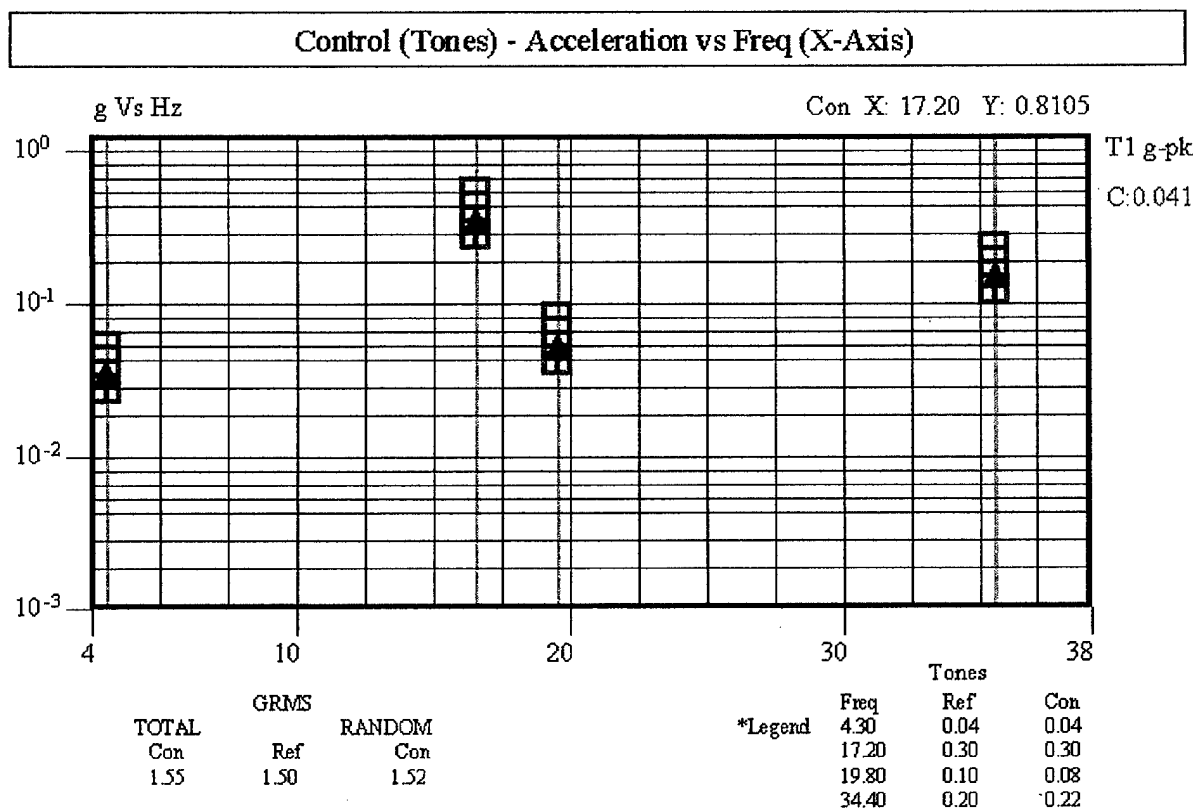


Figure 3. Helicopter (Sine-On-Random) X-Axis based on MIL-STD 810F

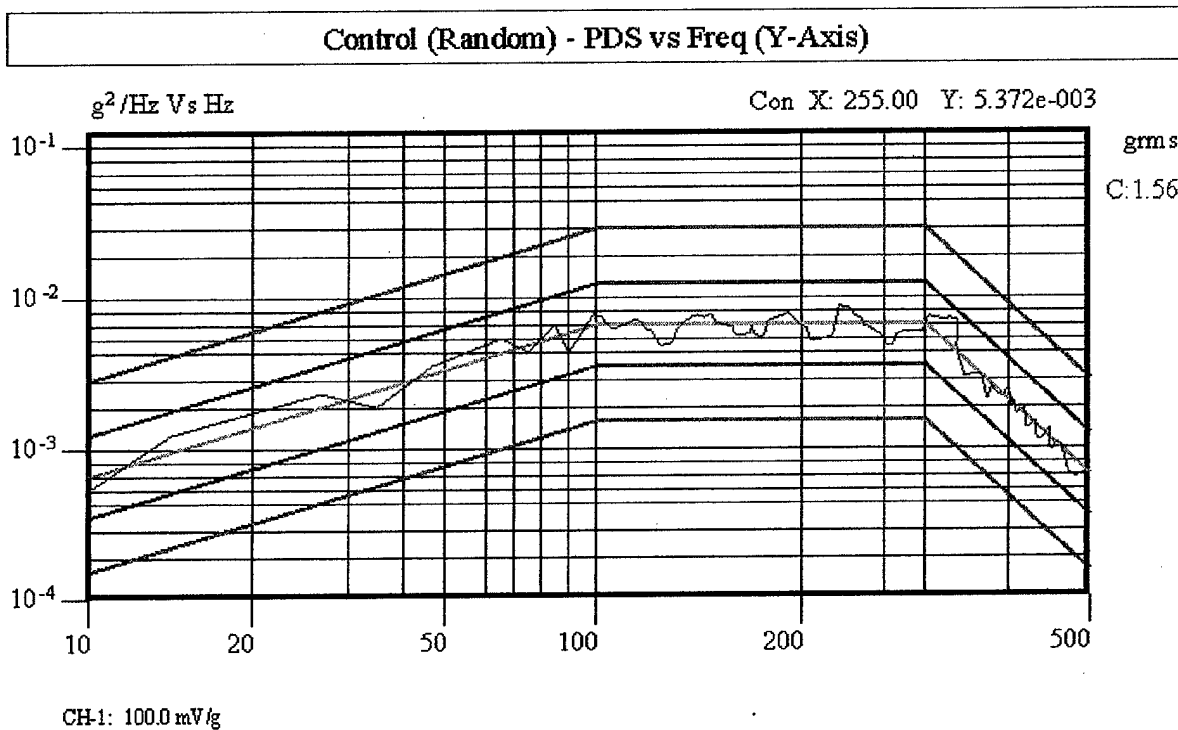
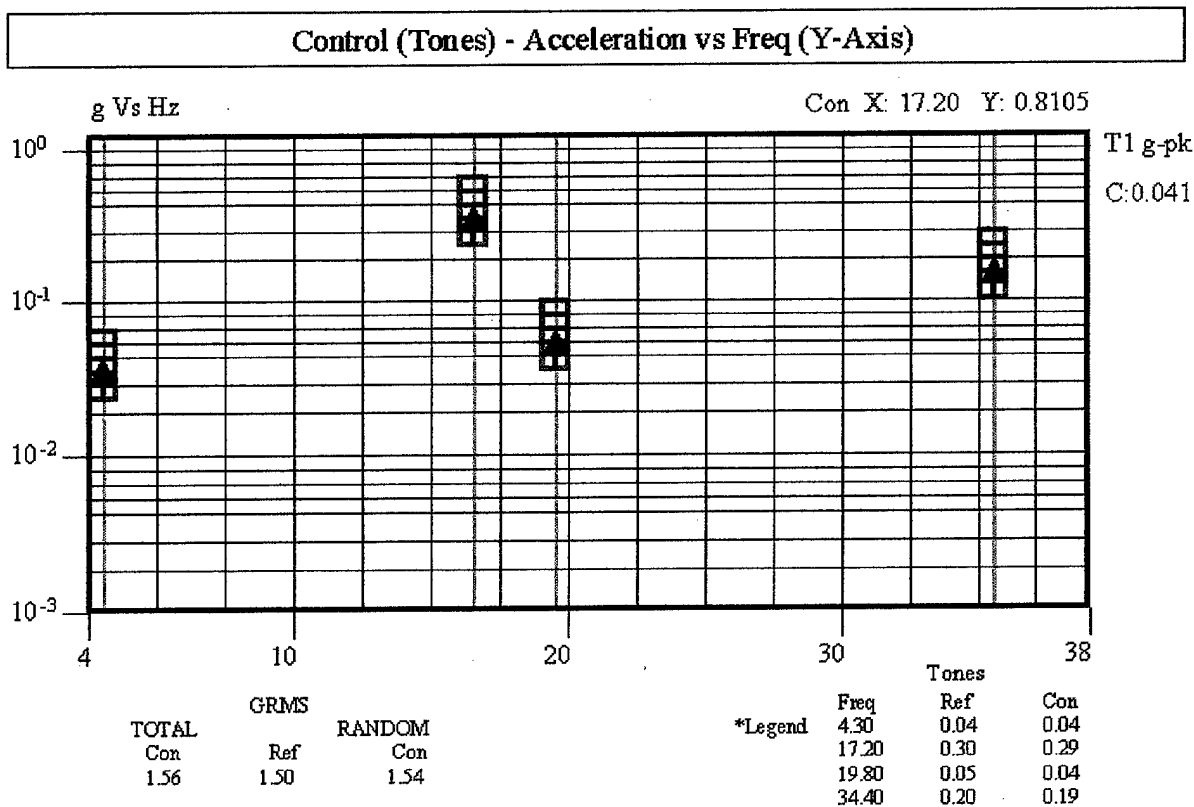
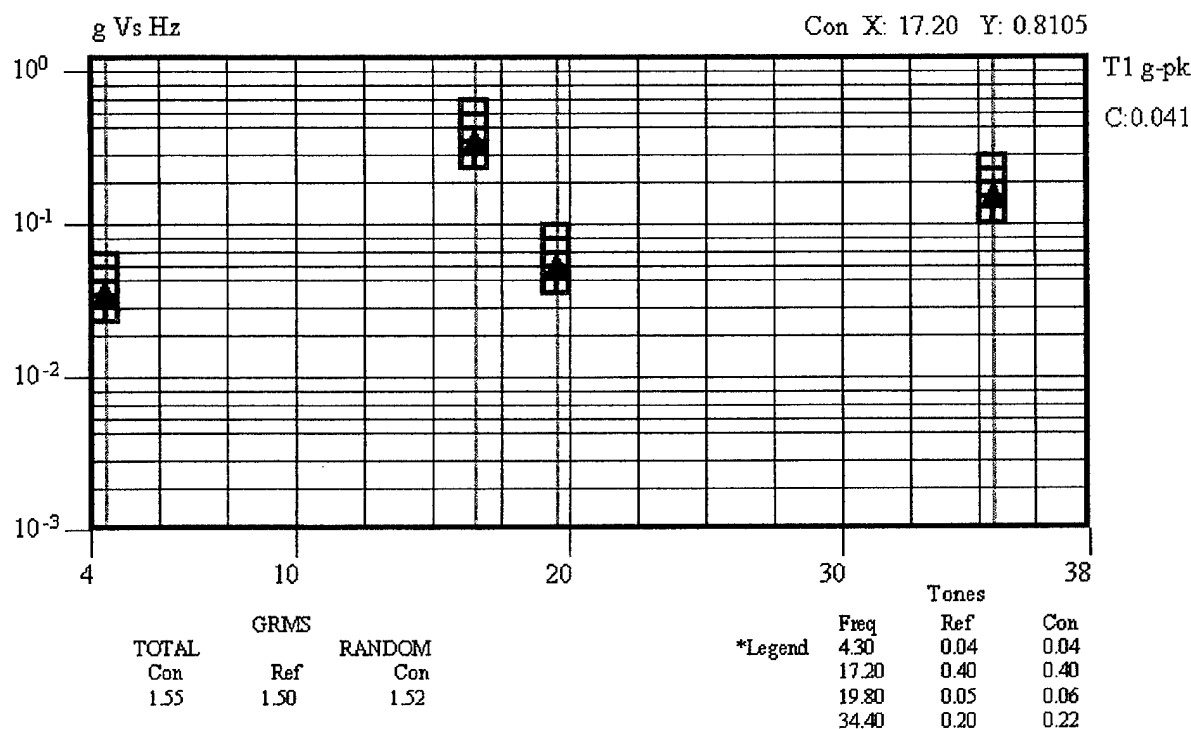


Figure 4. Helicopter (Sine-On-Random)Y-Axis based on MIL-STD 810F

Control (Tones) - Acceleration vs Freq (Z-Axis)



Control (Random) - PDS vs Freq (Z-Axis)

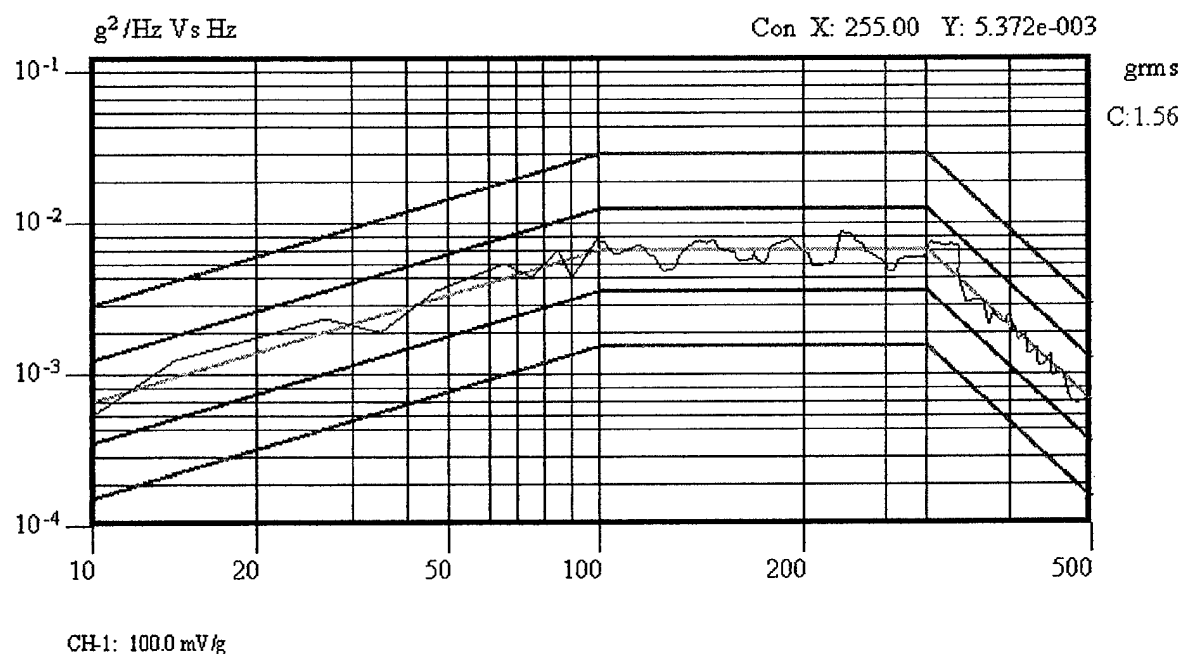


Figure 5. Helicopter (Sine-On-Random) Z-Axis based on MIL-STD 810F

Control (Random) - PDS vs Freq

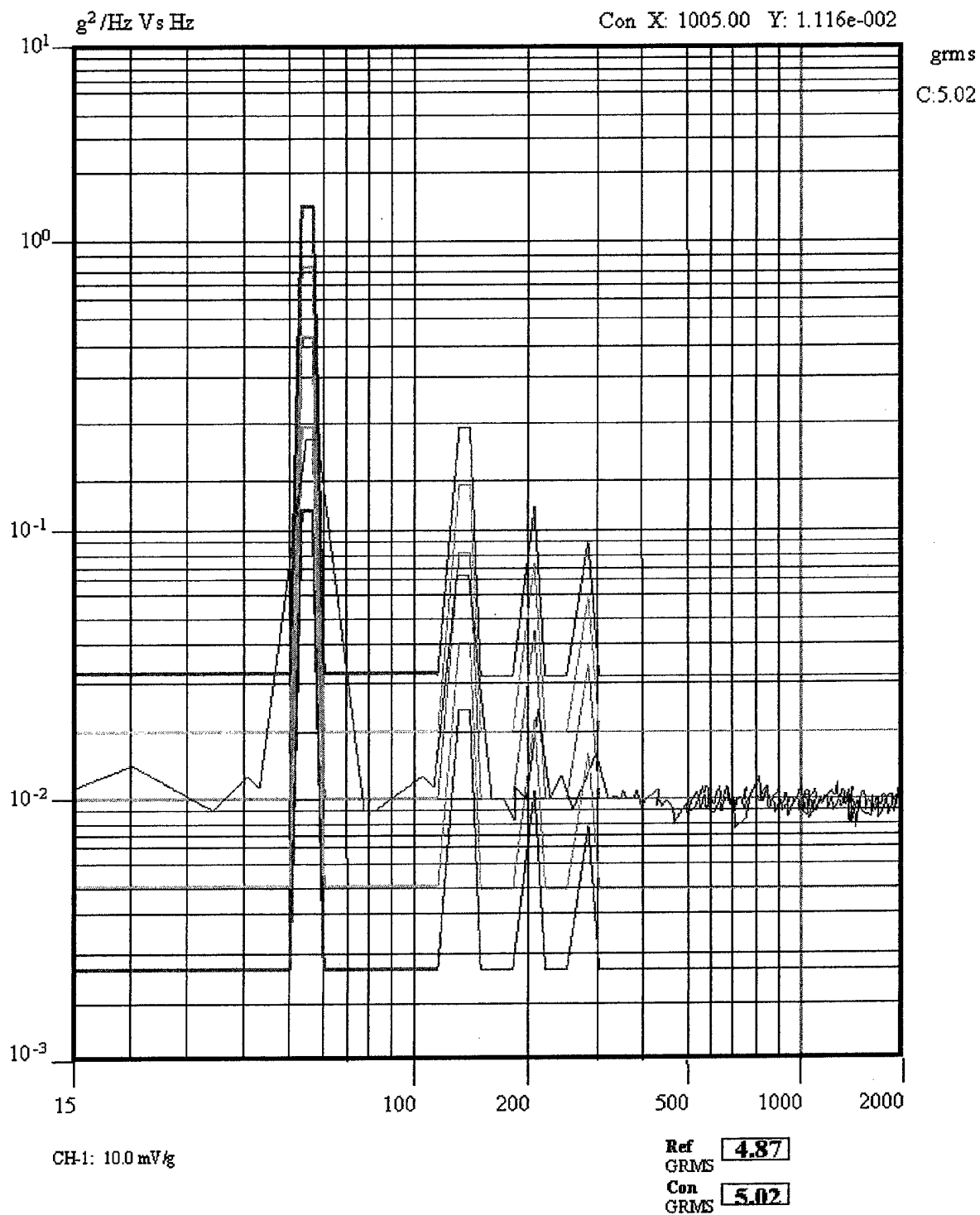


Figure 6. C-130 Turbo-prop based on MIL-STD 810F

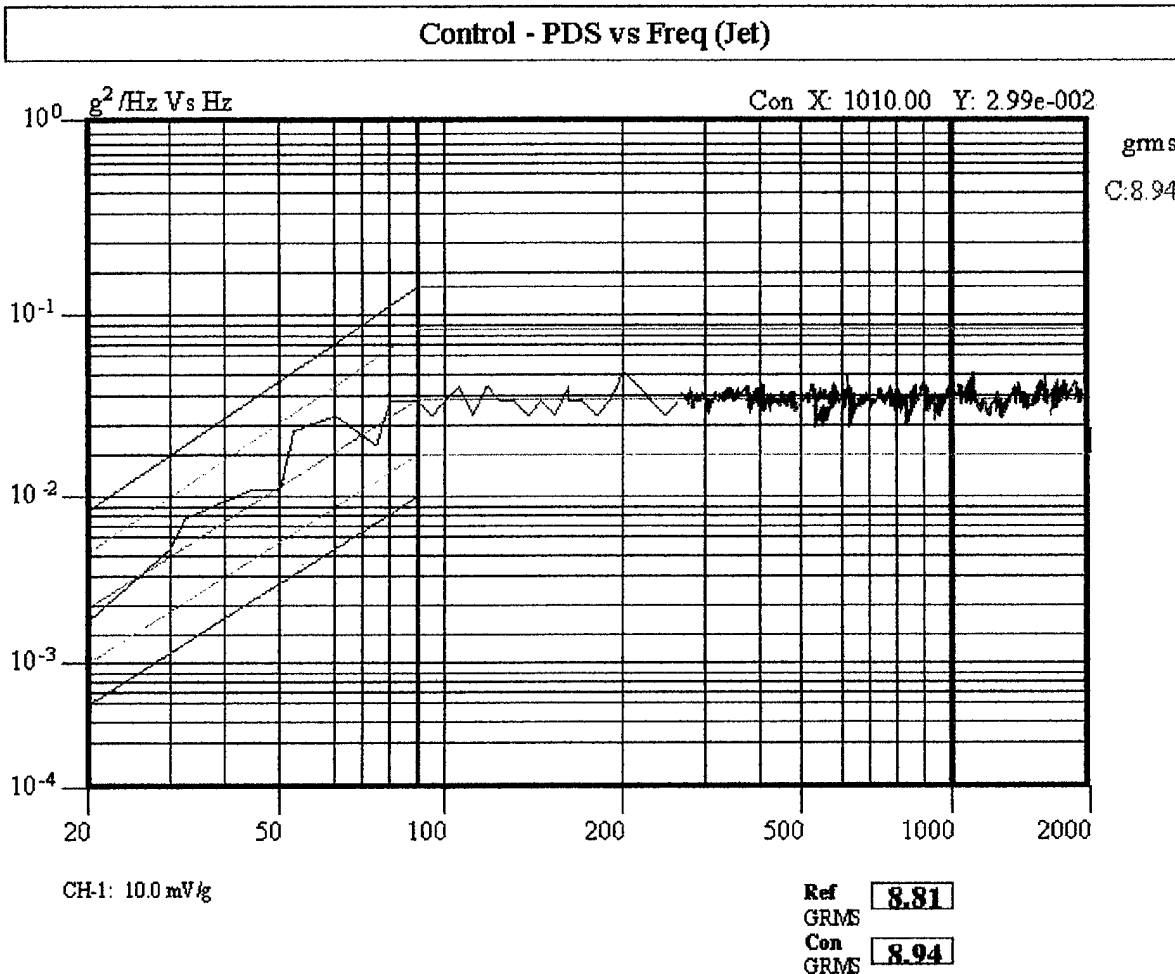


Figure 7. Jet Random based on MIL-STD 810F

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Ensuring the safety of everyone onboard is the driving factor to assessing the effects of excessive electromagnetic emissions and their influence on aircraft navigation and communication equipment. Medical devices may be susceptible to fields generated by the aircraft equipment or other medical devices and may malfunction in their presence.

The ZOLL Base PowerCharger^{4X4} was evaluated for compliance with MIL-STD 461E (2). AFRL/SNZW Electromagnetic Research Laboratory located at Wright-Patterson AFB along with ASC/ENAE performed the evaluation in their electromagnetic compatibility facility. WL/AAWA-2, Wright-Patterson AFB, evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

1. **RE102 - Radiated Emissions, Electric Field, (10 kHz - 18 GHz).** For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test which measured the amount of EMI emitted by the equipment during its operation, was performed to verify the EUT does not affect other pieces of equipment that may be susceptible to electromagnetic emissions (i.e., aircraft navigation and communication equipment).
2. **CE102 - Conducted Emissions, Power Leads, (10 kHz to 10 MHz).** For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test which measured emissions generated by the EUT along its power supply lines, was performed to verify that operating the EUT using line power does not affect other items connected to the same power source, particularly aircraft systems.
3. **RS103 - Radiated Susceptibility, Electric Field, (10 kHz to 40 GHz).** For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 18 GHz . This test evaluated the EUT's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.
4. **CS101 - Conducted Susceptibility, Power Leads, (30 Hz to 150 kHz).**
For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 150 kHz. This test determined the EUT's ability to withstand ripple voltages associated with allowable distortion of power source voltage waveforms.
5. **CS114 - Conducted Susceptibility, Bulk Cable Injection, (10 kHz to 400 MHz).** For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout a narrower portion of the frequency band, from 10 kHz to 200 MHz. This test determined whether simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the EUT.
6. **CS115 - Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation.** This test evaluated the EUT's resistance to the fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse.
7. **CS116 - Conducted Susceptibility, Damped Sinusoidal Transients, (10kHz to 100 MHz).** This test procedure is used to verify the ability of the EUT to withstand damped sinusoidal transients coupled onto the EUT's associated cables and power leads. This requirement is applicable to all interconnecting cables, including power cables, and individual high side power leads.

THERMAL/HUMIDITY

Extreme temperature and humidity testing is critical to determine if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical

damage or deterioration in performance. Extreme environmental conditions can have numerous incapacitating effects on medical equipment including but not limited to the following: changes in material characteristics and material dimensions; possible overheating; changes in lubricant viscosity; changes in electronic components; and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Air Force Research Laboratory (AFRL) research chambers operated and monitored by chamber operations personnel assigned to the Protective Systems Branch of the Biodynamics and Protection Division, AFRL, Brooks AFB, TX. The EUT was placed in the center of the environmental chamber. The power cable was routed through a port in the chamber wall, which was subsequently sealed with a sponge plug. For operational tests, the EUT was monitored continuously and a performance check was conducted every fifteen minutes. For storage tests, the EUT was placed in the chamber and remained operational throughout the storage portion of the test. It was then placed outside the chamber and brought to laboratory ambient conditions for 30 minutes before conducting an operational test. The following describes the conditions of the environmental tests performed:

- a. Humidity: $94 \pm 4\%$ RH, $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 4 hrs
- b. Hot Temp Operation: $120^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($49^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hrs
- c. Cold Temp Operation: $32^{\circ}\text{F} \pm 7.2^{\circ}\text{F}$ ($0^{\circ}\text{C} \pm 4^{\circ}\text{C}$) for 2 hrs
- d. Hot Temp Storage: $140^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($60^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hrs
- e. Cold Temp Storage: $-40^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($-40^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hrs

HYPOBARIC

Testing was conducted at the Air Force Research Laboratory (AFRL) chambers operated and monitored by chamber operation personnel assigned to the Protective Systems Branch of the Biodynamics and Protection Division, AFRL, Brooks AFB, TX.

1. Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft, which are characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 feet above sea level. The differences in pressures can be critical to the effective operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 15,000 feet. Performance checks were conducted at 2,000 foot intervals to assess the unit. The same performance checks were conducted during decent back to ground level, at rates of 5000 ft/min, while stopping every 2,000 feet to allow for additional performance checks.

2. **Rapid Decompression Testing:** Rapid decompressions are caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to determine how medical equipment will function during and after such a decompression to ensure that it will not endanger a patient, the aircrew personnel, or the aircraft itself. The EUT operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice with the decompressions occurring over seven and one seconds, respectively. The EUT was monitored throughout the series of decompressions, including performance checks each time the unit returned to ground.

EXPLOSIVE ATMOSPHERE

Testing was performed at the WRACC/TIECD (Engineering Test Facility) Robins AFB, Georgia. This test is conducted to assess the unit's safety while operating in a fuel-enriched and reduced hypobaric environment under simulated flight conditions. Testing is conducted based on guidance found in MIL-STD 810F, Method 511.4. A test report was generated at the end of testing and results were forwarded to AFMED for inclusion in this technical report (11).

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating a piece of equipment's clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their actual operational environment, AFMED ensures pertinent patient care issues are adequately addressed by the test protocols. Ensuring safe and reliable operation of this medical equipment support device is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection of the EUT revealed no manufacturing defects. The EUT performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits.

VIBRATION

Vibration testing of the EUT was conducted at the AFMED vibration facility. Initial vibration resulted in damage to resistors causing a power failure of the EUT. The unit was sent back to the company for system redesign. Upon return to AFMED the EUT successfully passed vibration testing with no failures.

ELECTROMAGNETIC COMPATIBILITY

The ZOLL Medical Corp., PowerCharger^{4X4} with Auto Test (Military Model 8050-0002-30), and PD 4410 rechargeable Smart batteries (model 8004-0103-30) were tested for electromagnetic interference (EMI) for conducted and radiated susceptibility requirements of MIL-STD 461E. The EUT as modified per military model met required limits for radiated and conducted susceptibility and are certified per Air Force Instruction (AFI) 11-202-V3 for use on all phases of flight on all USAF fixed-wing aircraft and helicopters.

THERMAL/HUMIDITY

The EUT operated satisfactorily during all five phases of testing.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing.
2. Rapid Decompression: The EUT operated satisfactorily following each decompression.

EXPLOSIVE ATMOSPHERE

Engineers at WRACC/TIECD, Robins AFB, GA evaluated the explosive atmosphere test data and determined the medical device did not pose an explosive atmosphere hazard.

AIRBORNE PERFORMANCE

This phase of testing was conducted on two aeromedical evacuation missions. The first mission was conducted onboard a C-9A Nightingale by an aeromedical research technician. The second mission was conducted onboard a C-130 by the Chief of AFMED. During both missions, the EUT was secured to a standard NATO litter and evaluated throughout all phases of flight by AFMED personnel as well as by other members of the aeromedical evacuation crew. Human factors, characteristics, securing methods, equipment setup times, and locations were assessed.

The inflight evaluations of the EUT confirmed that the unit would operate successfully during all phases of flight.



Figure 8. ZOLL Base PowerCharger^{4x4} onboard a C-9A Nightingale

SUMMARY

1. The test and evaluation of the ZOLL Medical Corp., PowerCharger^{4x4} with Auto Test (Model 8050-0002-30 Military), and PD 4410 rechargeable Smart batteries (model 8004-0103-30) has been completed. AFMED found the EUT "ACCEPTABLE" for use during all phases of flight on all USAF aircraft (including fixed and rotary wing). The EUT was also evaluated for compliance with MIL-STD 810F. WRACC/TIECD engineers at Robins AFB, GA evaluated the explosive atmosphere test data and determined the medical device did not pose an explosive atmosphere hazard. The EUT operated within expected parameters when subjected to environmental extremes and simulated cabin altitudes and did not demonstrate the potential for being a hazard to patients or crews during rapid decompression. Specific military part numbers were assigned to the EUT by the engineers at ZOLL Medical Corporation. The military^{4x4} Base PowerCharger with AutoTest is PN: 8050-0002-30; the military Smart Battery is PN: 8004-0103-30.
2. The following recommendations apply to the ZOLL Base PowerCharger^{4x4} while in the aeromedical evacuation environment:
 - A. Attach a "Caution" label on the ZOLL Base PowerCharger^{4x4} that reads, **"Do not operate on 115VAC/400 Hz."**
 - B. Do not place PowerCharger^{4x4} directly on a blanket when securing to NATO litter. Doing so may obstruct vents on the bottom of the unit and prevent proper dissipation of heat during operation. AFMED recommends aluminum brackets (Figure 8) be

used for securing or place on flat/firm surface such as a small section of smooth plywood. Litter straps should not obstruct vents.

- C. AFMED does not recommend that ZOLL Battery PD4410 or ZOLL Smart Battery PD4410 from the MonoPhasic and BiPhasic units be used with the ZOLL PD 4420 battery charger due to manufacturer's warnings about 4410 batteries overheating without special precautions being taken.
- D. Manufacturer recommends battery replacement every eighteen months or sooner.
- E. No transport case was evaluated. Care needs to be taken during transport to prevent damage to ZOLL Base PowerCharger ^{4x4}.
- F. AFMED anticipates aeromedical evacuation crewmembers will secure ZOLL ^{4x4} with litter straps causing obstruction of "Caution" label on top surface of unit. Recommend "Caution" label and ZOLL logo positions be switched.
- G. Recommend "Fault" light illumination be red instead of green for more noticeable display of fault indication.

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REFERENCES

1. ZOLL Base PowerCharger ^{4X4}, Operator's Manual.
2. MIL-STD 461E, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
3. MIL-STD 810F, Environmental Test Methods and Engineering Guidelines.
4. MIL-STD1472F, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
5. Emergency Care Research Institute (ECRI).
6. Air Force Medical Equipment Development Laboratory Flight Performance Evaluation Procedures Guide and Testing Standards, Protective Systems Branch
7. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code.
8. AFI 41-203, Electrical Shock Hazards.
9. AFI 41-201, Equipment Management in Hospitals.
10. MIL-STD 461E EMI Test Report # B01-1, AFRL/SNZW, WPAFB, OH
11. Explosive Atmosphere Test, Project 200052, WRALC/TIECD, Robins AFB, GA

APPENDIX

MANUFACTURER'S SPECIFICATIONS OF THE ZOLL MEDICAL, INC. POWERCHARGER^{4x4}

SPECIFICATIONS Base PowerCharger^{4x4}

General

Size	4.2 in. high x 13.2 in wide x 12.2 in long
Weight	4.1 kg (9.0 lbs) without batteries 8.1 kg (17.8 lbs) with 4 batteries
Power Requirements	110 VAC, 50-60 Hz input 220-240 VAC, 50-60 Hz input
Power Consumption	100 watts maximum
Design Standards	Designed to meet or exceed UL 544, IEC 601, and and CSA 22.2 standards for medical equipment safety.

Recharge Time

QuickCharge Four hours or less for total recharge of fully depleted Battery

AutoTest Eight hours or less for AutoTest and total recharge of battery.

Temperature 5°C to 40°C (operating)
15° to 35°C (optimal battery charging)
-40°C to 70°C (storage)

Humidity 5% to 95% relative humidity – non condensing

External Fuses 2 Type T, 2A/250V Slow Blow fuses located above AC mains input

Specifications
Batteries – PD 4410

General

Type	Rechargeable, sealed lead acid.
Weight	1 kg (2.2 lbs)
Size	4 cm high x 7 cm wide x 18.9 cm long (1.58 x 2.78 x 7.44 in.)
Nominal Battery Voltage	2.0 V/cell; 5 cells
Capacity	2.5 Amp Hour rating for new batteries.
Temperature	0°C to 55°C (operating) 15°C to 35°C (optimal battery charging) -40°C to 75°C (storage)
Humidity	5% to 95% (relative humidity – non condensing).
Service	Battery pack is easily removed as a unit.
Capacity Test	At a minimum, test batteries every three months. Refer to ZOLL's Battery Management Program